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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,408

11/30/2006

Leander Grode

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6449

7590

04/08/2008

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

04/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/554,408	Applicant(s) GRODE ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-17, 21-23, 25-30 and 32 is/are allowed.
- 6) ☒ Claim(s) 5, 18-20, 24, 31 and 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Preliminary Amendment, received 24 October 2005, is acknowledged. Claims 21, 22, 24, 25, 27, 32, and 33 have been amended.
2. Claims 1-38 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 7, line 27, "ascpect" should be "aspect".

Page 9, line 33, recites "each bar", but the figure utilizes symbols and lines. Clarification is required.

Page 10, line 23, "Kanamycine" should be "Kanamycin".

Page 11, line 36, "immunised" should be "immunized".

Page 12, lines 14, 17, and 23, "immunised" should be "immunized".

Page 13, line 3, it is unclear what is meant by "died until day 25".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Embodiment (b) of Claim 5 is drawn to a modified bacterial cell which comprises a nucleotide sequence which encodes for the same amino acid sequence as a nucleotide sequence "comprising" nucleotide 211-1722 as shown in SEQ ID NO:1.

Because of the open language, "comprising" the nucleotide sequence of embodiment can have any number of nucleotides on either end of the sequence 211-1722 as shown in SEQ ID NO:1, and as such can encode amino acid sequences from these unknown regions.

The nucleotide sequence in embodiment (b) therefore can be a sequence which encodes the same unknown amino acid sequences as embodiment (a). Thus, the identity of the claimed nucleotide sequence of embodiment (b) is indefinite.

Likewise, embodiment (c) is indefinite because the claimed nucleotide sequence may hybridize to the unknown regions of the nucleic acids of embodiments (a) and (b).

6. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a bacterial cell comprising at least one recombinant nucleic acid molecule encoding a peptide or polypeptide and which comprises at least one further recombinant nucleic acid molecule encoding a peptide or polypeptide.

The relationship between the first "at least one" and the second "at least one further" molecule is indefinite concerning whether the molecules are identical or different.

Claims 19 and 20 are dependent claims, but do not clarify the issue.

7. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 24 is drawn to a bacterial cell which is urease-deficient and which comprises a recombinant nucleic acid molecule. The bacterial cell has an intracellular persistence in infected macrophages which is equal or less than the intracellular persistence of a native Mycobacterium cell.

The claim is unclear because: a) the genus/species of the claimed bacterial cell is unknown, and b) its persistence is to be compared to any unidentified species of Mycobacterium whose intracellular persistence varies greatly.

8. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a bacterial cell comprising at least one recombinant nucleic acid molecule encoding a peptide or polypeptide and which comprises at least one further recombinant nucleic acid molecule encoding a peptide or polypeptide.

The relationship between the first "at least one" and the second "at least one further" molecule is indefinite concerning whether the molecules are identical or different.

9. Claims 33-38 provide for the use of a modified bacterial cell, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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11. Claims 33-38 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

12. Claims 5, 18-20, 24, 31, and 33-38 are rejected.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 30, 2008